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10/627,867	07/28/2003	Henri Hannula	0365-0568P	3629
2252	7590	11/29/2010	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH			DOWE, KATHERINE MARIE	
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FALLS CHURCH, VA 22040-0747			3734	
NOTIFICATION DATE		DELIVERY MODE		
11/29/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/627,867	<b>Applicant(s)</b> HANNULA ET AL.
	<b>Examiner</b> KATHERINE M. DOWE	<b>Art Unit</b> 3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 15 September 2010.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 26-49 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 26-49 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. The following is in response to the amendment filed September 15, 2010.
2. Claims 26-49 are currently pending.

***Claim Objections***

3. Claims 26, 37, and 43 are objected to because of the following informalities: The claims initially recite a *stereotactic device* (line 1 of claim 26 and line 2 of claim 37). However, line 11 of claim 26 and lines 5 and 13 of claim 37 refer to a *stereostatic device*. Furthermore, claim 37 initially refers to a stereotactic *frame* (lines 2 and 5) and later refers to a stereotactic *device* (line 13) and dependent claim 43 additionally later refers to a stereotactic *device* (line 2). The Examiner is interpreting each limitation to be referring to the same element; however, the claims should be amended for consistent language.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 26-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding claims 26 and 37, there is insufficient support in the application for the limitation: the stereostatic device is "configured so that the frame stays immobile during *any* facial movements". The examiner notes some facial movements, in particular movements of the nose, may cause the frame to move at least slightly.

Additionally regarding claims 26, there is insufficient support in the application for the limitation: the stereostatic device is "configured to contact the subject at only one point of contact on a front of a face of the subject", wherein the stereostatic device is defined as comprising the frame and the means for securing the frame. The examiner notes the means for securing the frame is defined as an elastic band that passes behind the head, which does not contact the patient at only one point of contact on a front of a face of the subject. For the purpose of examination, the claim is interpreted such that the frame contacts the subject at only one point of contact on a front of a face of the subject.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 26-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 26, it is unclear how the stereostatic device is "configured to contact the subject at only one point of contact on a front of a face of the subject", wherein the stereostatic device is defined as comprising

the frame and the means for securing the frame. The examiner notes the means for securing the frame is defined as an elastic band that passes behind the head, which does not contact the patient at only one point of contact on a front of a face of the subject. For the purpose of examination, the claim is interpreted such that the frame contacts the subject at only one point of contact on a front of a face of the subject.

***Claim Rejections - 35 USC § 102***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. With regard to applicant's "means for securing the frame" of claim 26, the language appears to be an attempt to invoke 35 USC 112, 6<sup>th</sup> paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for " or "step for; "
- (B) the "means for " or "step for " must be modified by functional language; and
- (C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for clarification.

In the specification, applicant defines the "means for securing the frame" as an adjustable band. Accordingly, the examiner is interpreting the "means for securing the

frame" to encompass an adjustable band and its equivalents. Equivalent structures may include those that perform the function specified in the claim, structures that are not excluded by any specific definition provided in the specification for an equivalent, or is a structural equivalent of the corresponding element disclosed in the specification. See MPEP 2183.

10. Claims 32-34 are not being treated under 35 U.S.C. 112, sixth paragraph, because the claim limitations recite sufficient structure and/or acts for achieving the specified function of the "means for securing the frame".

11. Claims 26-32, 35-43, 46, and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferre et al. (US 6,694,167). Ferre et al. disclose a stereotactic device comprising a frame (102) configured to mount on the nasion of a subject extending frontally below the eyes to end positions of the frame that are in front of the face of the subject such that the frame is capable of staying immobile during facial movements of the subject (Figs 1 and 18). All portions of the frame (102) are capable of being located below the eyes and a forehead of the subject. At least three fiducial markers (116) are mounted on the frame and configured to define a position of the frame with respect to the subject, wherein at least three of the fiducial markers are in different vertical lines from one another, the vertical lines being perpendicular to the frame (Figure 18, col 8, ll 25-32). The frame includes a nasion relator portion comprising a nose piece (32) compliant with a contour of the subject's nose. A means for securing the frame to a head of the subject comprises a supporting element (30/34), wherein the supporting

element is attached to the end positions of the frame and secured to the subject so as not to immobilize the head of the subject. Ferre et al. further discloses a diagnostic method comprising mounting the frame on the nasion of the subject, defining a position of the frame with respect to the subject via the three fiducial markers, and performing a diagnosis based on the defined position of the frame with respect to the subject (col 2, II 19-37; col 8, ln 3 – col 9, ln 26).

***Claim Rejections - 35 USC § 103***

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
13. Claims 33, 34, 44, 45, 48, and 49 rejected under 35 U.S.C. 103(a) as being unpatentable over Ferre et al. (US 6,694,167), as applied to claims 32 and 43 above, in view of Anthony (US 6,758,218). Ferre et al. disclose the invention substantially as claimed as shown above including an adjustable supporting element (30/34) to secure the frame to the subject. However, Ferre et al. do not disclose the supporting element is an adjustable band that passes behind the subject's head, neck, or shoulders such that the supporting element forms a closed loop. Anthony discloses a similar device with a frame (500) configured to be mounted on a subject's face (Figure 9) and teaches the frame is fixed on the subject with an adjustable band (510) that extends laterally from the frame and passes behind the subject's head (col 23, II 22-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Ferre et al. such that the supporting element

comprised an adjustable band that passes laterally from the frame (102) and behind the subject's head to more securely hold the frame in place on the subject's face. When the device of Ferre et al. is modified in this manner, the supporting element would also be capable of securing the frame to the head of the subject so as not to immobilize the head of the subject.

#### ***Response to Arguments***

14. Applicant's arguments filed September 15, 2010 have been fully considered but they are not persuasive.

15. Applicant argues the device of Ferre et al. comprises a nose bridge (32) on center member (34) and two ear mounts (28) on side members (30) of the headset. Thus, Applicant contends the device contacts the forehead, both sides of the head, the two ears, and portions of the face above and between the two eyes. The examiner agrees the entire device comprising the frame (102) and the means for securing the frame (headset including center member 34, side members 30, and ear mounts 28) contact the patient at several points including the side of the head. However, the frame itself (102) only contacts the patient on the nasion of the subject through the nose bridge (32). The examiner notes the claim must be interpreted such that the *frame*, rather than the entire device comprising the means for securing the frame, contacts the subject at only one point since Applicant discloses the means for securing the frame (adjustable band 4) contacts additional points not on a front of a face of the subject (Applicant's Fig 4).

16. Applicant argues it is not proper to select a single portion, such as center member 34 of the head set 12, to define the claimed frame of the present invention. The examiner respectfully disagrees and reiterates the center member 34 is clearly one element of the entire device comprising the frame, fiducial markers, nasion relator portion, and supporting element. The examiner notes if the center member cannot be considered a separate element, then by the same argument Applicant's "frame", "fiducial markers", "nasion relator portion", and "supporting element" cannot be considered separate elements making up the claimed stereotactic device.

17. Applicant argues Ferre et al. discloses multiple distinct embodiments and it is not proper to combine features from two distinct alternative embodiments. The examiner acknowledges distinct features of alternative embodiments may not be inherently combined if not taught in the reference as a combination. However, when discussing the embodiment of Figures 18-19, Ferre et al. disclose, "For example, as shown in FIGS. 18 and 19 another embodiment of a headset 100 of the invention includes two ear mounts 28, side members 30, and a nose bridge mount 32 on center member 34 as discussed above with reference to FIGS 2-4" (col 8, ll 5-8; emphasis added).

18. Applicant additionally argues Ferre et al. does not teach the stereotactic device is configured so that the frame stays immobile during any facial movements of the subject. The examiner notes the frame is capable of staying immobile during facial movements of a subject, such as during movements of the patient's mouth, which is not contacted by the frame. It is noted Applicant has provided no evidence to establish an unobvious difference between the claimed product and the prior art, but rather has merely argued

such alleged difference. Mere arguments can not take the place of evidence. *In re Walters*, 168 F.2d 79,80, 77 USPQ 609,610 (CCPA 1948); *In re Cole*, 326 F.2d. 769,773, 140 USPQ 230,233 (CCPA 1964); *In re Schulze*, 346 F.2d 600,602, 145 USPQ 716,718 (CCPA 1965); *In re Lindner*, 457 F.2d 506,508, 173 USPQ 356,358 (CCPA 1972); *In re Pearson*, 494 F.2d 1399,1405, 181 USPQ 641,646 (CCPA 1974); *Meitzner v. Mindick*, 549 F.2d 775,782, 193 USPQ 17,22 (CCPA), cert. Denied, 434 U.S. 854 (1977); *In re DeBlauwe*, 736 F.2d 699,705, 222 USPQ 191,196 (Fed. Cir. 1984).

### ***Conclusion***

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe  
November 19, 2010

/K. M. D./  
Examiner, Art Unit 3734

/TODD E. MANAHAN/

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